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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,151	04/16/2002	Takashi Shigematsu	56501-002001	8643

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EXAMINER	
VENCI, DAVID J	
ART UNIT	**PAPER NUMBER**
1641	

NOTIFICATION DATE	DELIVERY MODE
04/14/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORTPATENT.COM

Office Action Summary	Application No.	Applicant(s)	
	10/009,151	SHIGEMATSU ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *April 9, 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-27,29-57,59 and 62-67* is/are pending in the application.

4a) Of the above claim(s) *22-26 and 30-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27,29,59 and 62-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *22-27,29-57,59 and 62-67* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 9, 2007 has been entered.

Claims 22-27, 29-57, 59 and 62-67 are pending in this application.

Claims 22-26 and 30-57 are direct to non-elected inventions and apparently were withdrawn from consideration pursuant to 37 CFR 1.142(b) in the Office Action dated July 13, 2005.

Claims 27, 29, 59, 62-67 are now under examination.

Specification

The disclosure is objected to because of the following informalities:

On p. 2, line 9; p. 5, lines 24-25, and; p. 6, line 27, the phrase "varying experimental reagent" is not clear. How Applicants subject a reagent to "varying" is not clear.

On p. 3, lines 15-16, the phrase "collect a large number of blood samples denatured lipoprotein" is not clear because the identity of a "blood samples denatured lipoprotein", or the object subject to "collect" is not clear.

On p. 4, line 17, the identity of a "reconstructive lipoprotein", or how a lipoprotein is "reconstructive" or "reconstructed", or how a "reconstructive lipoprotein" is derived is not clear.

On p. 5, line 7, the phrase "incorporating into blood plasmlipoprotein" is not clear because the identity of a "plasmlipoprotein", or the object subject to oxide "incorporation" is not clear.

The sentence bridging pp. 5-6 is incomprehensible because it severally contains too many commas and semicolons.

On p. 6, line 1, the phrase "severally containing lipoprotein' is not clear. How Applicants subject a lipoprotein to "severally containing" is not clear.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 67 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 67, the preamble does not correspond to the method outcome because the preamble intent of "producing a stabilized denatured oxidized lipoprotein" appears accomplished upon performance of "freeze-drying". The purpose of extraneous step of "determining an amount of the denatured lipoprotein" is not clear.

Claim 67 is further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Specifically, whether/how performing the step of "freeze-drying" results in an "oxidized lipoprotein" is not clear. One or more steps of "oxidizing" appear omitted from the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness[1] rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27, 29, 59, 62-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimura *et al.* (PTO 07-6676, English translation of JP 09-2881064) in view of Proksch & Bonderman (US 4,216,117).

Kimura *et al.* describe a method for producing a denatured lipoprotein standard (see Title, "lipoprotein oxide and standard substance").

Kimura *et al.* do not teach the claimed steps of: freezing, melting, mixing and freeze-drying.

However, Proksch & Bonderman describe:

1. freezing a first solution containing lipoproteins (see *e.g.*, col. 3, line 59, "serum which is frozen");

2. melting the frozen solution to produce a melted solution (see *e.g.*, col. 3, line 59, "serum which is[...] thawed") of denatured lipoprotein (see e.g., col. 3, lines 57-58, "those lipoproteins which are associated with the turbidity");

[1] In the Supreme Court decision *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), the Court set forth factual inquiries establishing a background for determining obviousness under 35 U.S.C. 103(a). The factual inquiries include: (1) determining the scope and contents of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the pertinent art; and (4) considering objective evidence indicating obviousness or nonobviousness.

3. mixing (see *e.g.*, col. 3, line 60, "reconstituted") a stabilizing agent (see *e.g.*, col. 3, line 66, "lipoprotein diluent"; see *also*, lines 67-68, "turbidity-potential lipoproteins"; see *also*, col. 4, line 48, "preservative"; see *also*, lines 50-52, "polyhydroxy cryoprotective agent, an antibiotic or antiseptic agent"; see *also*, lines 66-68, "ethylene glycol, diethylene glycol, propylene glycol and butylenes glycol, sorbitol, glucose, lactose and sucrose"; see *also*, col. 5, lines 5-6, "penicillin, gentimycin, tetracycline and bacitracin"; see *also*, line 17, "serum constituents"; see *also*, line 23, "carbonate compound"; see *also*, lines 30-31, "sodium bicarbonate, tris bicarbonate, and ammonium bicarbonate"; see *also*, lines 36-39, "sodium chloride, ammonium chloride, tris chloride, tris acetate, sodium acetate, and ammonium acetate, and tris-ethylenediamine tetraacetic acid") with the melted solution to produce a second solution; and

4. freeze-drying the second solution (see col. 6, lines 27-28, "the final serum standard to be lyophilized").

It would have been obvious for persons of ordinary skill to perform Proksch's & Bonderman's protocol on Kimura's denatured lipoprotein standard because Proksch & Bonderman say lipoproteins, in general, "cause significant turbidity upon lyophilization and reconstitution" (see col. 2, lines 34-37), which Proksch's & Bonderman's protocol apparently obviates by providing a lipoprotein standard that "does not result in a significant increase in the turbidity" (see col. 2, lines 46-50).

Response to Arguments

In prior Office Action, claim 27 was rejected under 35 U.S.C. 103(a) as being unpatentable over Kamarei (US 4,749,522) in view of Proksch & Bonderman (US 4,216,117). In addition, claims 27, 29, 58-60 and 62-64 were rejected under 35 U.S.C. 103(a) as being unpatentable over Magneson & Reichenbach (US 5,547,873) in view of Proksch & Bonderman (US 4,216,117).

Notwithstanding Applicants' argumentation on these issues, these rejections are withdrawn.

Conclusion

No claims are allowable at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Assistant Examiner
Art Unit 1641

djv

LONG V. LE
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